

Attorney Docket No. PC9517H  
Application No. 10/615,282

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REMARKS

The Finality of the Instant Office Action

The office action dated February 14, 2007 was made final as Applicant's previous amendment allegedly necessitated new grounds of rejection. Applicant respectfully submits that the previous amendment to the claims was in response to a restriction requirement and was not in response to the instant grounds of rejection. Thus, the finality of the instant office action is premature. In view of this, Applicant respectfully requests the Examiner to reconsider and withdraw the finality of the instant Office Action.

Amendments to the Specification

The previous title "Use of Estrogen Antagonists and Estrogen Agonists in Inhibiting Pathological Conditions" has been deleted and replaced with the new title "Use of Estrogen Antagonist/Agonists in Inhibiting Inflammatory Bowel Disease." Support for this amendment is in the specification as originally filed, particularly at page 2, line 32; page 8, line 2 and in view of the original title.

The previous abstract has been deleted and replaced with a new abstract. The new abstract is specifically directed to methods of inhibiting inflammatory bowel disease with a compound of formula I. Support for this amendment is in the specification as originally filed, particularly at page 2, line 32; page 8, line 2 and in view of the abstract as originally filed.

Objection to the Title

The title of the subject application has been objected to as allegedly not being descriptive of the claimed invention. The previous title "Use of Estrogen Antagonists and Estrogen Agonists in Inhibiting Pathological Conditions" has been replaced by the present amendment with the new title "Use of Estrogen Antagonist/Agonists in Inhibiting Inflammatory Bowel Disease." Applicant submits that the title, as amended, is fully descriptive of the claimed invention. Applicant respectfully requests the Examiner to consider the title, as amended, and withdraw the objection.

Objection to the Abstract

The abstract has been objected to as allegedly not being directed to the presently claimed subject matter. The previous abstract has been replaced with a new abstract that is directed to methods of inhibiting inflammatory bowel disease with a compound of formula I. Applicant respectfully submits that the abstract, as

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amended, is directed to the presently claimed subject matter. Applicant respectfully requests the Examiner to consider the abstract, as amended, and withdraw the objection.

**The 35 U.S.C. § 112, First Paragraph Rejection**

Claims 23-26 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and not being enabled. Applicant traverses this rejection.

The claimed invention is a method of inhibiting inflammatory bowel disease with a compound of formula I, compounds within that genus or pharmaceutically acceptable salts thereof. Applicant respectfully submits that instant claims 23-26 are fully enabled such that one of ordinary skill in the art could employ the compounds of formula I in inhibiting inflammatory bowel disease in a patient in need thereof.

The specification provides compounds of formula I and denotes particular species within formula I at page 3, line 5 through page 7, line 28. The compounds of formula I or pharmaceutically acceptable salts thereof can be prepared according to the methods as described at page 26, line 20 through page 33, line 30 of the specification. Methods of determining the estrogenic and/or anti-estrogenic potential of the compounds of formula I are provided at page 38, line 22 through page 39, line 8 of the specification. The potency of the compounds of formula I can be determined according to the estrogen receptor binding assay as provided at page 39, lines 9-28 of the specification. Methods of administering the compounds for the inhibition of inflammatory bowel disease are described in the specification at page 34, lines 1-26. The specification also provides for various dosages, dosage regimens, and pharmaceutical compositions for the compounds of formula I at page 34, line 27 through page 38, line 21 of the specification.

One of ordinary skill in the art would clearly be enabled by the guidance provided in the specification to use a compound of formula I for inhibiting inflammatory bowel disease in a patient in need thereof by following the direction as provided in the specification. The claims are directed to a method of inhibiting inflammatory bowel disease using the genus of formula I and preferred species within that genus. Applicant respectfully submits that the claims are of appropriate breadth in view of the detailed description provided. Applicant further submits that undue experimentation would not be required in view of the specific direction provided in the instant specification. Compounds of formula I and preferred particular species within formula I have been clearly disclosed and one skilled in the gastrointestinal art could

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readily employ these compounds in the claimed method as described. One of ordinary skill in the gastrointestinal art is clearly enabled by the specification to administer a compound of formula I, at an appropriate dosage, in an appropriate dosage form and according to an appropriate dosage regimen to a patient in need of inhibition of inflammatory bowel syndrome.

For this reason, Applicant respectfully requests the Examiner to reconsider and withdraw the 35 U.S.C. § 112, first paragraph rejection in view of the preceding comments.

Conclusion

Applicant believes that, in view of the amendments to the specification and the remarks made above, this application is in condition for allowance. Entry of the amendments to the specification and reconsideration and allowance of claims 23-26 is respectfully requested.

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